

REMARKS

Claim of Priority under 35 U.S.C. §120

In the February 2, 2010 Office Action, the Office stated that the:

“Instant claims do not get the effective filing date of the provisional application, i.e., 09/16/2002, due to lack of support there in for the limitation ‘TSV capsid protein’ recited in the independent claims 17 and 21.”

Applicants vigorously disagree.

United States Provisional Application No. 60/410,818, filed September 9, 2002, provides ample support for the term “TSV capsid protein.” The provisional application specifically states on page 3, the following:

In one embodiment of the invention a method of protecting an animal from viral infection is provided. The method comprises the steps of:

Production of a viral protein, such as a capsid or envelope protein, in a foreign host expression system, such as in a yeast, fungus, bacterium, alga, insect, animal, or plant, or alternatively in tissue/cell cultures of these systems.

Processing the biomass containing the viral protein into a feed or feed supplement with minimal purification,

Providing the biomass to the animal to deliver the viral protein in an amount up to 0.5 to 50 % of the total animal feed content,

Wherein the presence of the viral protein competes with live virus inside the animal to prevent infection.

Thus the applicants have provided support for use of a viral capsid and viral diseases such as TSV is discussed in the “Background of the Invention” on page 2, as shown below:

Viral diseases cause a huge amount of economic loss in crustacean aquaculture. A number of viruses are important to shrimp aquaculture and cause billions of dollars worth of damage annually with virtually no therapeutic treatment available to combat this problem. Yellow head virus (YHV), Taura syndrome virus (TSV), infectious hypodermal and hematopoietic necrosis virus (IHHNV) and White spot syndrome virus (WSSV) have caused pandemics that have affected global penaeid shrimp farming (Lightner 2002).

It is well settled in the law that for a prior application to meet the "written description" requirement with respect to later-filed claims, the prior application need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the earlier date the applicant had invented what is now claimed. *Vas-Cath Inc. v. Mahurkar*, 19, USPQ 2d 1111, (Fed. Cir. 1991); see *In re Wertheim*, 191 USPQ 90 (CCPA 1976) ("[L]ack of literal support . . . is not enough . . . to support a rejection under Section 112.") The test is whether the disclosure of the application relied upon reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 USPQ 177 (Fed. Cir. 1985). Clearly, from reading the priority application it is evident that the viral protein can be from numerous viruses including the viral capsid of TSV. Further one skilled in the art would understand that the examples for the viral capsid protein of one virus that being WSSV can be easily transferred to a TSV capsid protein.

As such, applicants respectfully request that all claims recited in the present application be given the effective filing date of September 16, 2002.

Rejections of Claims and Traversal Thereof

In the February 2, 2010 Office Action,

claims 17-20, 23-26 and 32-34 were rejected under 35 U.S.C. §112, second paragraph;

claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(1) as being anticipated by Kyle (US 2004/0047881);

claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(2) as being anticipated by Sayre, et al. (US Patent No. 7,410,637); and

claim 34 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle et al. (US 2004/0047881) or Sayre, et al. (US Patent No. 7,410,637), in view of Nakamura et al, JP 200354490 (abstract).

The above-defined rejections are hereby traversed, and reconsideration of the patentability of the pending claims is requested, in light of the ensuing remarks.

Rejections under 35 U.S.C. §112, second paragraph

Claims 17-20, 23-26 and 32-34 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for multiple reasons.

Initially, it should be noted that the phrase “a recombinant viral protein or peptide” seems to be causing a considerable amount of confusion. It should be noted that both the protein and peptide are recombinant and they share the article “a” in claim 17. In claim 18, the article is changed to “the” and both of the terms “protein” or “peptide” share this article. According to most third grade English text used by students in the US, this is acceptable. Thus, the inclusion of the article “the” before the term “peptide” is not required in claim 18 or any other dependent claims.

According to the Office, claim 17 and all claims depending therefrom should read as follows:

17. A feed for an animal comprising one or more recombinant viral protein or peptide from white spot syndrome virus (WSSV) or Taura Syndrome Virus (TSV) that inhibits or retards binding to viral receptors in the gut of the animal, wherein the viral receptors are needed for WSSV or TSV infection, wherein the recombinant viral protein or **the** peptide is selected from the group consisting of VP24, VP28, VP26, VP19, and TSV capsid protein.

Applicants believe that the introduction of the article “the” at the position requested by the Office introduces ambiguity into the claims because now the term “peptide” stands alone and is no longer connect to the terms “recombinant viral.” This is not what applicants intended and it is well settled in the law that applicants are allowed a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. §112, second paragraph. Further, the Office may not dictate the literal terms of the claims, and more important, how the applicants claim the invention is within applicants’ discretion. See *In re Tanksley*, 37 USPQ2d 1382 (BPAI 1994).

Applicants have addressed all other 112 rejections and request the withdrawal of same.

Rejections under 35 U.S.C. §102(e)

1. Claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(1) as being anticipated by Kyle (US 2004/0047881). Applicants submit that, as discussed above, the present invention has an effective

filing date before the effective filing date of Kyle. As such this reference is not competent prior art and this rejection should be withdrawn.

2. Claims 17-26 and 32-33 were rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Sayre, et al. (US Patent No. 7,410,637). Applicants submit that this reference is not anticipatory and does not defeat the patentability of the presently claimed invention.

Applicants' claim 17 recites the following:

17. A feed for an animal comprising one or more expressed recombinant viral protein or peptide from white spot syndrome virus (WSSV) or Taura Syndrome Virus (TSV), wherein the recombinant viral protein or peptide binds to and blocks viral receptors needed for WSSV or TSV infection in the gut of the animal, wherein the recombinant viral protein or peptide is selected from the group consisting of VP24, VP28, VP26, VP19, and TSV capsid protein.

Anticipation under 35 U.S.C. § 102 requires the presence, in a single reference, of each and every element of the claimed invention, **arranged as in the claim**. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). The Sayre reference does not meet this standard.

Sayre teaches the induction of an immune response and never discloses, teaches or suggests the binding of receptors in the gut of an animal consuming the expressed recombinant proteins. According to the Office:

"Since the prior art one or more recombinant proteins, VP28, VP24, VP26 or VP19 are the same as Applicants', the capacity to block viral receptors needed for WSSV infection in one or more cells of the animal is viewed as the intrinsic property inseparable from the prior art one or more recombinant proteins or peptides VP28, VP24, VP26, or VP19."

Applicants disagree and state that the Office, in relying on an intrinsic property which is a theory of inherency, must provide a basis in fact or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teaching of the applied prior art. See *In re Robertson*, 29 USPQ2d 1949 (Fed. Cir. 1999).

The Office has not provided persuasive support for an inherent theory. Inherency cannot be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of

circumstances is not sufficient to establish inherency. *In re Oelrich*, 212 USPQ 323 (CCPA 1981). Instead, it must consistently occur each and every time, which is necessary under case law to prove inherency. Clearly, causing an immune response such as in Sayre is not analogous to blocking of receptor sites. There is an important distinction between sitting and blocking a receptor site, as in the present invention and that of Sayre with a free protein with an epitope that induces an immune response. This distinction highlights the flaw in the Office's hypothetical that an induction of an immune response anticipates the blocking of a receptor.

In light of the above discussion, applicants request the withdrawal of all anticipation rejections.

Rejection under 35 U.S.C. §103(a)

Claim 34 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle et al. (US 2004/0047881) or Sayre, et al. (US Patent No. 7,410,637), in view of Nakamura et al, JP 200354490 (abstract). Applicants insist that the proposed combination does not in any way establish a *prima facie* case of obviousness.

As previously stated, Kyle is not considered to be competent prior art, and the Sayre reference does not teach or suggest all the claim elements of the presently claimed invention. The addition of Nakamura does not overcome the shortcomings of the Sayre reference.

There is nothing in the Sayre reference that would infer the binding to and blocking of viral receptors. The Court's decision in *In re Spormann*, 150 USPQ 449 (CCPA 1966), bears directly on point:

“The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown”

Hence, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 28 USPQ2d 1955 (Fed. Cir. 1993). Here the binding and blocking of the viral receptors was unknown. Therefore, how could a skilled artisan make any modification while arriving at an invention that possesses the heretofore unknown characteristic. While it is possible that, serendipitously, the invention would have such a feature, serendipity is not a valid basis for asserting obviousness.

As such, the proposed combination does not defeat the patentability of the presently claimed invention and applicants request the withdrawal of this obviousness rejection.

Rejoinder of Method Claims

When an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

The currently pending method claims include all the limitations of the product claims and meet all standards of enablement, written description and definiteness under 35 U.S.C. §112. Accordingly, the method claims are in form suitable for future examination upon their rejoinder with the allowed product elected claims. Applicants are requesting that all method claims be rejoined, examined and found allowable.

Petition for Extension and Fees Payable

Applicants petition for a one month extension to extend the response due date of May 2, 2010 to June 2, 2010 and the fee of \$65.00 is being paid herewith by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

Conclusion

Applicants have satisfied all the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Devi reconsider the patentability of pending claims in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. If any issues remain outstanding incident to the prosecution of the application, Examiner Devi is requested to contact the undersigned attorney at (919) 286-8089.

Respectfully submitted,

/mariannefuierer/

Marianne Fuierer
Reg. No. 39,983
Attorney for Applicant

Moore & Van Allen, PLLC
Telephone: (919) 286-8000
Facsimile: (919) 286-8199